

## PATENT COOPERATION TREATY

**PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 165WOa-1	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2005/005393	International filing date (day/month/year) 24 March 2005 (24.03.2005)	Priority date (day/month/year) 24 March 2004 (24.03.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant DAINIPPON SUMITOMO PHARMA CO., LTD.			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																
<p>3. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).</p>	<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of issuance of this report 18 October 2006 (18.10.2006)	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer  Masashi Honda e-mail: pt08@wipo.int

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

**PCT**

**TRANSLATION**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference <b>165WOa-1</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/JP2005/005393</b>	International filing date (day/month/year) <b>24.03.2005</b>	Priority date (day/month/year) <b>24.03.2004</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>DAINIPPON SUMITOMO PHARMA CO., LTD.</b>		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
**PCT/JP2005/005393**

Box No. I	Basis of this opinion
<p>1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p>	
<p>2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p>	
<p>3. <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>	
<p>4. Additional comments:</p>	

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2005/005393

Box No. IV      Lack of unity of invention

1.  In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
  - paid additional fees
  - paid additional fees under protest
  - not paid additional fees
2.  This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
  - complied with
  - not complied with for the following reasons:

The inventions of independent claims 1, 2 and 3 relate to a garment for bioinformation measurement wherein a breast induction electrode section for acquiring the electrocardiographic potential near the breast when a subject wears the garment is arranged, and the garment is formed of a nonconductive material. The inventions of independent claims 7 and 8 relate to an electrocardiogram analyzer, or a computer-readable program for allowing a computer to function as an electrocardiogram analyzer. The inventions of independent claims 15 and 16 relate to an aspiration information analyzer or a computer-readable program for allowing a computer to function as an aspiration information analyzer. The invention of claim 20 relates to an electrocardiogram analyzer control method. The invention of independent claim 21 relates to an aspiration information analyzer control method. There is no technical relationship among these inventions involving one or more of the same or corresponding special technical feature. Consequently, these inventions cannot be considered to be so linked as to form a single general inventive concept.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
  - all parts
  - the parts relating to claims Nos. \_\_\_\_\_

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
**PCT/JP2005/005393**

Box No. V		Reasoned statement under Rule 43(bis, I(a)(i)) with regard to novelty, inventive step or Industrial applicability; citations and explanations supporting such statement																									
<p><b>1. Statement</b></p> <table> <tr> <td align="center">Novelty (N)</td> <td align="center">Claims</td> <td align="center"><u>1, 4, 6-21</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center"><u>2, 3, 5</u></td> <td align="center">NO</td> </tr> <tr> <td align="center">Inventive step (IS)</td> <td align="center">Claims</td> <td align="center"><u>1, 6-9, 14-21</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center"><u>2, 3, 4, 5, 10-13</u></td> <td align="center">NO</td> </tr> <tr> <td align="center">Industrial applicability (IA)</td> <td align="center">Claims</td> <td align="center"><u>1-21</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center">_____</td> <td align="center">NO</td> </tr> </table>				Novelty (N)	Claims	<u>1, 4, 6-21</u>	YES		Claims	<u>2, 3, 5</u>	NO	Inventive step (IS)	Claims	<u>1, 6-9, 14-21</u>	YES		Claims	<u>2, 3, 4, 5, 10-13</u>	NO	Industrial applicability (IA)	Claims	<u>1-21</u>	YES		Claims	_____	NO
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	Claims	_____	NO																								

**2. Citations and explanations:**

Document 1: JP 2002-159458 A (Fukuda Denshi Co., Ltd.), 04 June 2002, paragraphs 0029-0034, Figs. 1, 2 (Family: none)

Document 2: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 123433/1989 (Laid-open No. 139608/1990) (Wacoal Corp.), 21 November 1990, Specification, page 6, line 14 to page 7, line 2, Fig. 1 (Family: none)

Document 3: IP 2002-35141 (Yasutake NICCHI), 05 February 2002, paragraphs 0030-0040, Figs. 2-6 (Family: none)

Document 4: IP 10-99299 A (Director General, Agency of Industrial Science and Technology), 21 April 1998, paragraphs 0018-0019, Figs. 1, 2 (Family: none)

**Claim 1**

Documents 1-3 do not describe a garment for bioinformation measurement wherein, when a subject wears the garment, breast induction electrode sections having length that covers from the body surface near the forth rib to the body surface near the sixth rib are arranged at 6 locations or more, between the position in contact with the vicinity of the front part of the chest bone and the position in contact with the vicinity of the side part of the left chest side of the subject; nor is this obvious to a person skilled in the art.

**Claims 2, 4, 5**

Document 1 describes a shirt for bioinformation measurement wherein a breast induction electrode section formed of a conductive material having the length of 8.5 cm in the body length direction of the garment is arranged near the front center part of the garment to near the left hem of the garment. Also, providing the breast induction electrode section at a position from near the front part of the chest bone towards near the side part of the right chest of the subject is described. The inventions described in claim 2 and 5 are disclosed in document 1.

Also, although the shirt described in document 1 covers the body surface near the clavicles of the subject, in the garment for bioinformation measurement, providing a four-limb conductive electrode part in addition to the breast induction is described in document 2, and therefore, in the invention described in document 1, further providing the four-limb conductive electrode part could easily be conceived by a person skilled in the art.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Claim 3

Document 3 describes a garment for bioinformation measurement formed of a nonconductive material provided with an electrode for living body near the chest part of a subject. The invention described in claim 3 is disclosed in document 3.

Claims 6-9, 20

Documents 1 through 5 do not describe outputting an electrocardiogram data by comparing the amplitude of a plurality of electric potential information based on electric potentials transmitted from a plurality of breast induction electrode sections, selecting a breast induction electrode section with large amplitude as electric potential information for the basis of electrocardiogram output based on the comparison result, and analyzing the electric potential information of the selected breast induction electrode section; nor is obvious to a person skilled in the art.

Claim 10-13

In document 4, a garment for bioinformation measurement wherein an aspiration information measurement sensor section which comprises a conductive member wherein, in a turned-on state, electric resistance value varies by contraction in accordance with a physical change by aspiration movement of a subject and allows transmission of electric information based on that variation in electric resistance value to an aspiration information analyzer is described. Providing also the aspiration information measurement sensor to the garment for bioinformation measurement described in documents 1 and 3 is obvious to a person skilled in the art.

Claims 14-19, 21

Document 4 does not describe outputting aspiration information data by comparing the amplitude of a plurality of electric information obtained by a plurality of aspiration information measurement sensor sections, selecting an aspiration information measurement sensor section with large amplitude as electric information for the basis of aspiration information output based on the comparison result, and analyzing aspiration information based on the fluctuation cycle of the electric information of the selected aspiration information measurement sensor section; nor is this obvious to a person skilled in the art.

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<p>Date of issuance of this report 26 September 2006 (26.09.2006)</p>	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Authorized officer  Masashi Honda e-mail: pt08@wipo.int

# 特許協力条約

発信人 日本国特許庁（国際調査機関）

代理人

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E K第2ビル

REC'D 14 JUL 2005

WIPO

PCT

P C T  
国際調査機関の見解書  
(法施行規則第40条の2)  
(PCT規則43の2.1)

12.7.2005

発送日 (日.月.年) 12.7.2005

今後の手続きについては、下記2を参照すること。

出願人又は代理人  
の書類記号 165W0a-1

国際出願番号 PCT/JP 2005/005393	国際出願日 (日.月.年) 24. 03. 2005	優先日 (日.月.年) 24. 03. 2004
------------------------------	-------------------------------	-----------------------------

国際特許分類 (IPC) Int.Cl.<sup>7</sup> A61B5/04, 5/08

出願人 (氏名又は名称)  
大日本製薬株式会社

1. この見解書は次の内容を含む。

- 第I欄 見解の基礎
- 第II欄 優先権
- 第III欄 新規性、進歩性又は産業上の利用可能性についての見解の不作成
- 第IV欄 発明の單一性の欠如
- 第V欄 PCT規則43の2.1(a)(1)に規定する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるための文献及び説明
- 第VI欄 ある種の引用文献
- 第VII欄 国際出願の不備
- 第VIII欄 国際出願に対する意見

2. 今後の手続き

国際子供審査の請求がされた場合は、出願人がこの国際調査機関とは異なる国際子供審査機関を選択し、かつ、その国際子供審査機関がPCT規則66.1の2(b)の規定に基づいて国際調査機関の見解書を国際子供審査機関の見解書とみなさない旨を国際事務局に通知していた場合を除いて、この見解書は国際子供審査機関の最初の見解書とみなされる。

この見解書が上記のように国際子供審査機関の見解書とみなされた場合、様式PCT/ISA/220を送付した日から3月又は優先日から2月のうちいずれか遅く摘要した期限が経過するまでに、出願人は国際子供審査機関に、適当な場合は補正書とともに、答弁書を提出することができる。

さらなる選択肢は、様式PCT/ISA/220を参照すること。

3. さらなる詳細は、様式PCT/ISA/220の備考を参照すること。

見解書を作成した日

21.06.2005

名称及びあて先

日本国特許庁 (ISA/JP)

郵便番号 100-8915

東京都千代田区霞が関三丁目4番3号

特許庁審査官、(権限のある職員)

門田 宏

電話番号 03-3581-1101 内線 3290

2Q 9224

## 第1欄 見解の基礎

1. この見解書は、下記に示す場合を除くほか、国際出願の言語を基礎として作成された。

この見解書は、\_\_\_\_\_語による翻訳文を基礎として作成した。  
それは国際調査のために提出されたPCT規則12.3及び23.1(h)にいう翻訳文の言語である。

2. この国際出願で開示されかつ請求の範囲に係る発明に不可欠なスクレオチド又はアミノ酸配列に関して、  
以下に基づき見解書を作成した。

a. タイプ

配列表  
 配列表に関連するテーブル

b. フォーマット

書面  
 コンピュータ読み取り可能な形式

c. 提出時期

出願時の国際出願に含まれる  
 この国際出願と共にコンピュータ読み取り可能な形式により提出された  
 出願後に、調査のために、この国際調査機関に提出された

3.  さらに、配列表又は配列表に関連するテーブルを提出した場合に、出願後に提出した配列若しくは追加して提出した配列が出願時に提出した配列と同一である旨、又は、出願時の開示を超える事項を含まない旨の陳述書の提出があった。

4. 捷足意見：

## 第IV欄 発明の單一性の欠如

1. 追加手数料納付の求め（既式PCT/ISA/206）に対して、出願人は、
  - 追加手数料を納付した。
  - 追加手数料の納付と共に異議を申立てた。
  - 追加手数料の納付はなかった。
2.  国際調査機関は、発明の單一性の要件を満たしていないと判断したが、追加手数料の納付を出願人に求めないととした。
3. 国際調査機関は、PCT規則13.1、13.2及び13.3に規定する発明の單一性を次のように判断する。
  - 満足する。
  - 以下の理由により満足しない。
 

独立請求の範囲1、2、3に記載される発明は、被験者が装着した際に胸部附近の心電位を取得する胸部誘導電極部が配置されている非導電性素材で形成された生体情報計測用衣服であり、独立請求の範囲7、8に記載される発明は、心電図解析装置又はコンピュータを心電図解析装置として機能させるためのコンピュータ読み取可能なプログラムであり、独立請求の範囲15、16に記載される発明は、呼吸情報解析装置又はコンピュータを呼吸情報解析装置として機能させるためのコンピュータ読み取可能なプログラムであり、独立請求の範囲20に記載される発明は、心電図解析装置制御方法であり、独立請求の範囲21に記載される発明は、呼吸情報解析装置制御方法である。これらの発明は、一又は二以上の同一又は対応する特別な技術的特徴を含む技術的な関係にないから、單一的一般的発明概念を形成するように連関しているものとは認められない。
4. したがって、国際出願の次の部分について、この見解書を作成した。
  - すべての部分
  - 請求の範囲\_\_\_\_\_に関する部分

第V欄 新規性、進歩性又は産業上の利用可能性についてのPCT規則43の2.1(a)(i)に定める見解、  
それを裏付ける文献及び説明

## 1. 見解

新規性 (N)	請求の範囲 1,4,6-21 請求の範囲 2,3,5	有 無
進歩性 (IS)	請求の範囲 1,6-9,14-21 請求の範囲 2,3,4,5,10-13	有 無
産業上の利用可能性 (IA)	請求の範囲 1-21 請求の範囲	有 無

## 2. 文献及び説明

文献 1 : JP 2002-159458 A (フクダ電子株式会社) 2002. 06. 04, 段落【0029】-【0034】、図1,2 (ファミリーなし)

文献 2 : 日本国実用新案登録出願1-123433号(日本国実用新案登録出願公開2-139608号)の願書に添付した明細書及び図面の内容を撮影したマイクロフィルム(株式会社ワコール), 1990. 11. 21, 明細書第6頁第14行目-第7頁第2行目、図1 (ファミリーなし)

文献 3 : JP 2002-35141A (日地 康武) 2002. 02. 05, 段落【0030】-【0040】、図2-6 (ファミリーなし)

文献 4 : JP 10-99299 A (工業技術院長) 1998. 04. 21, 段落【0018】-【0019】、図1,2 (ファミリーなし)

## ・請求の範囲 1

文献1-3には、被験者が装着した際には、被験者の第4肋骨付近の体表から第6肋骨付近の体表までを覆う長さを有する胸部誘導電極部が、被験者の胸骨前部付近に接する位置から左胸側部付近に接する位置の間の少なくとも6箇所に配置される生体情報計測用衣服は記載されておらず、これは当業者にとって自明でもない。

## ・請求の範囲 2, 4, 5

文献1には、衣服前面中央部付近から衣服左縁付近において、衣服身丈方向に約8.5 cmの長さを有する導電性素材で形成した胸部誘導電極部が配置されている生体情報計測用のシャツが記載されている。そして、被験者の胸骨前部付近から右胸側部付近に向かう位置に胸部誘導電極部を設けることも記載されている。請求の範囲2, 5に記載される発明は文献1に開示されている。

また、文献1に記載されたシャツは被験者の鎖骨付近の体表を覆うものであるが、生体情報計測用衣服において、胸部誘導に加えて四肢誘導電極部を設けることは文献2に記載されているので、文献1に記載されたものにおいて四肢誘導電極部を更に設けることは当業者が容易に想到しうることである。

## 補充欄

いざれかの欄の大きさが足りない場合

第 V 欄の続き

・請求の範囲 3

文献 3 には、被験者の胸部付近に生体用電極を設けた非導電性素材で形成された生体情報計測用衣服が記載されている。請求の範囲 3 に記載された発明は文献 3 に開示されている。

・請求の範囲 6-9, 20

文献 1 乃至 5 には、複数の胸部誘導電極部から伝達される電位に基づく複数の電位情報の振幅を比較し、比較結果に基づき心電図出力の基礎にする電位情報として振幅が大きい胸部誘導電極部を選択し、選択された胸部誘導電極部の電位情報を解析して心電図データを出力することは記載されておらず、当業者にとって自明でもない。

・請求の範囲 10-13

文献 4 には、被験者の呼吸動作による体格変動に伴って収縮することにより、通電状態において電気抵抗値が変化する導電性部材を含み、その電気抵抗値の変化に基づく電気情報を呼吸情報解析装置へ伝達可能な呼吸情報計測センサ部が配置された生体情報計測用衣服が記載されている。文献 1, 3 に記載された生体情報計測用衣服に該呼吸情報計測センサ部を併設することは当業者に自明のことである。

・請求の範囲 14-19, 21

文献 4 には、複数の呼吸情報計測センサ部から取得した複数の電気情報の振幅を比較し、比較結果に基づき呼吸情報の出力の基礎にする電気情報として振幅が大きい呼吸情報計測センサ部を選択し、選択された呼吸情報計測センサ部の電気情報の変動周期に基づいて呼吸情報を解析して呼吸情報データを出力することは記載されておらず、当業者にとって自明でもない。